



## Sizing Fenestrated Aortic Stent-grafts

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### KEYWORDS

Fenestrated EVAR;  
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**Abstract** *Introduction:* Fenestrated aortic stent-grafts are increasingly being used to treat patients with juxtarenal abdominal aortic aneurysms (AAA). Sizing of these stent-grafts is critical to ensure success and requires detailed expert assessment of aortic morphology. At present little is known about how sizing of these stent-grafts varies between observers and the necessary tolerances involved to ensure a successful procedure.

*Methods:* CT scans of 19 consecutive patients with juxtarenal aortic aneurysms that underwent successful endovascular repair with fenestrated stent-grafts were selected. Sizing of fenestrated aortic stent-grafts was performed independently by four experienced endovascular surgeons and results were compared. Data from the stent-graft manufacturer was available for comparison in 12 cases.

*Results:* All observers agreed on the number of fenestrations; 16 devices had 3 fenestrations and 3 had 4. The overall inter-observer measurement error for all target vessel orientation was  $\pm 12.6^\circ$  (10.8–14.4 95% CI), and for distance between target vessels  $\pm 5.3$  mm (4.4–6.2 95% CI). The median difference in internal stent-graft diameter was 1 stent size. Agreement on fenestration type ranged from (84–95%). Comparison was performed with the manufactured stent-graft in 12 cases. The overall mean difference of target vessel orientation between the manufactured devices and the four observers was  $-1.3^\circ$  (SD  $\pm 6.9$ ,  $-3.8$ – $1.2$  95% CI). There was less agreement between observers and device manufacturers on body and limb lengths and distal limb diameters.

*Conclusions:* There was generally a high level of agreement between experienced endovascular surgeons in sizing the fenestrated stent component. There were differences in component lengths but these could have been accommodated by varying the degree of overlap between components.

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## Introduction

Fenestrated aortic stent-grafts are increasingly being used to treat juxtarenal abdominal aortic aneurysms (AAA) as outcomes appear favourable when compared with open surgery.<sup>1–3</sup> However, there are limitations of this new technique, including high treatment costs, delay in manufacturing a custom made device, availability and complexity.<sup>4</sup> The techniques' success depends critically upon appropriate sizing of the stent-graft to ensure aneurysm exclusion and maintenance of visceral branch perfusion.<sup>4–6</sup> This process is labour intensive and has in the majority of cases been performed by the manufacturer in a centralized planning facility. These issues contribute to the expense of the technique, treatment delay and potentially limit its more widespread application.

Current aortic stent-graft technology houses the fenestrations for visceral vessel perfusion in a single tubular component which is the proximal part of a modular bifurcated system (Zenith Fenestrated, Cook Medical, Brisbane, Australia). Fenestrations may be in the form of scallops, large or small fenestrations (Fig. 1a). Accurate determination of visceral branch orientation (clock face position or orientation angle) and displacement from proximal stent-graft edge and other visceral branches is essential to obtain a satisfactory result.<sup>5,6</sup>

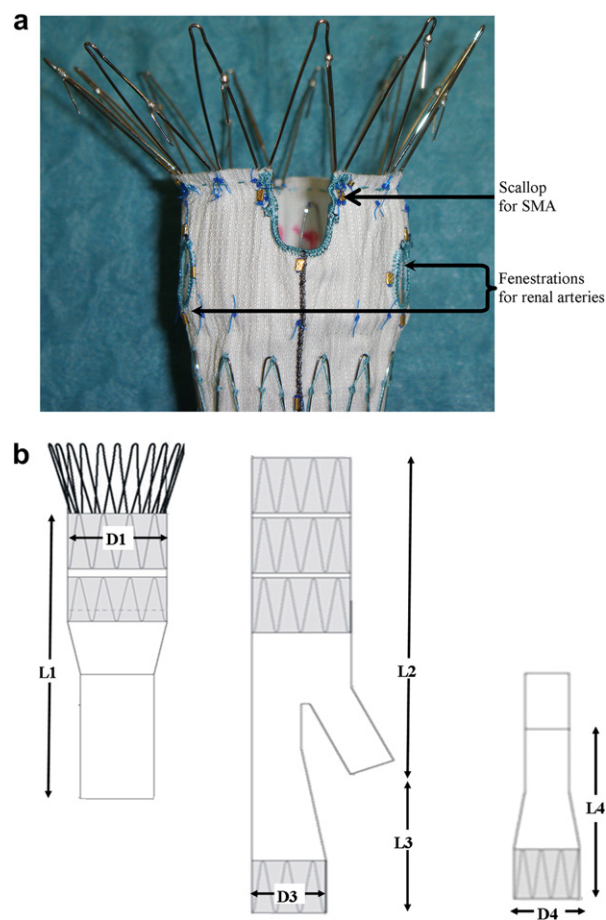
At present, little is known about the differences and implications of sizing aortic stent-grafts between different specialists and between clinicians and the manufacturer. This study investigates the variability in planning endovascular aneurysm repair using fenestrated stent-grafts by appropriately trained experienced endovascular specialists working independently in different institutions and compares them with industry measurements.

## Methods

Computed tomography scans of 19 consecutive patients with juxtarenal aortic aneurysms that underwent successful endovascular repair with a fenestrated aortic stent-graft (Zenith Fenestrated, Cook Medical, Brisbane, Australia) were selected for this study. Preoperative CT aortic protocol was performed for all patients (GE Lightspeed VCT, GE Healthcare, WI, USA) with iodinated contrast (Omnipaque 350, Nycomed Amersham, NJ, USA) injected at 4 ml/s (SmartPrep, GE Healthcare). Axial images were acquired at 0.625 mm intervals.

## Morphological measurement and planning

Four vascular surgeons (TR, MB, BM, and RH) with experience in fenestrated EVAR and planning from four different institutions were asked to independently assess and plan fenestrated aortic stent-grafts. Each author was provided with a digital versatile disc (DVD) of anonymised CT scans and a standardised proforma. Specific guidance on obtaining measurements was deliberately avoided and observers were asked to obtain measurements and plan stent-grafts as they would in their routine clinical practice. Three dimensional reconstruction software was used by all observers. Briefly, digital imaging and communications in medicine (DICOM) files were imported into a 3D workstation and with the aid of



**Figure 1** a: Proximal stent showing scallop for the SMA and two fenestrations for the renal arteries. b: Fenestrated stent-graft components with corresponding lengths and diameters used for device planning. Proximal graft diameter (D1), proximal graft length (L1), distal body length (L2), ipsilateral limb length (L3), contralateral limb length (L4), ipsilateral limb diameter (D3) and contralateral limb diameter (D4).

a workflow assistant, the aorta was segmented, bony skeleton excluded and a centre lumen line defined in preparation for measurement. Tera Recon software (Tera Recon Inc., San Mateo, CA, USA.) or 3mensio Vascular™ (3Mensio Medical Imaging, Bilthoven, The Netherlands) was used.

Surgeons were asked to assess the morphology of the aneurysm and then plan a suitable standard fenestrated aortic stent-graft. Measurements performed (Fig. 1b) included the internal aortic stent-graft diameter (D1), number of internal (sealing) stents, and number of fenestrations. Target vessel orientation (clock face position then converted to degrees for analysis considering 12 O'clock as 0°, the angle of each target vessel was measured relative to other target vessels), distance from the bottom edge of the coeliac axis and fenestration size (scallop, large or small). Proximal and distal body lengths and diameters were also collected. Proximal graft length (L1), distal body length (L2), ipsilateral limb length (L3), contralateral limb length (L4), ipsilateral limb diameter (D3) and contralateral limb diameter (D4). In addition, in 12 cases, device planning data was obtained from the stent-graft manufacturer and compared with measurements and recommendations from the 4 observers.

## Statistical analysis

Data were collected, entered into a database and analyzed (GraphPad Prism 5, GraphPad Software, Inc. CA, USA). Inter-observer variability for continuous variables was expressed as inter-observer measurement error and 95% confidence interval. The measurement error was calculated from the mean standard deviation of the difference in measurement as performed by the four observers per target vessel for orientation (difference of angle between each target vessel) and distance and averaged for all patients. Comparison with manufactured device data was expressed as the mean difference in measurement, standard deviation (SD) and 95% confidence interval.

For discrete variables, median and range were used to express inter-observer variability. Orientation was represented in degrees (°) and distance between coeliac axis (CA), superior mesenteric artery (SMA), left and right renal arteries (LRA, RRA respectively) in mm. One way analysis of variance (ANOVA) was used to detect any significant difference between target vessel orientation measurements (SMA, LRA and RRA) and distance between CA, SMA, LRA and RRA. In 12 cases the resultant values were also compared with available data from that which was designed from the central planning facility of the stent-graft manufacturer.

## Results

### Computed tomography image quality

CT image quality was considered satisfactory for 3 dimensional reconstruction in 96% (73/76) of occurrences. Although scan quality was considered suboptimal in the remaining 3, this did not preclude performing the measurements and stent-graft planning.

### Inter-observer variability in morphological assessment and stent-graft planning

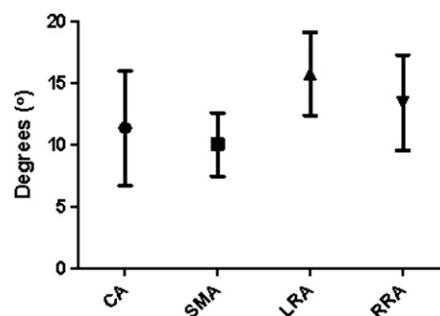
#### Aortic morphology

**Number of fenestrations.** All observers agreed on the number of fenestrations for each case; 16 devices had 3 fenestrations and the remainder had 4 fenestrations.

**Target vessel orientation.** 60 target vessels were analysed for agreement between observers regarding target vessel orientation. The overall inter-observer measurement error for all target vessel orientation was  $\pm 12.6^\circ$  (10.8–14.4 95% CI). The inter-observer measurement error of the orientation of the CA was  $11.4^\circ$  (6.7–16.0 95% CI); for the SMA  $\pm 10.1^\circ$  (7.5–12.6 95% CI); for the LRA  $\pm 15.8^\circ$  (12.4–19.2 95% CI); and for the RRA  $\pm 13.4^\circ$  (9.6–17.3 95% CI) (Fig. 2). There was no significant variance in the difference in measurement of target vessel orientation between CA, SMA, LRA and RRA (ANOVA,  $P = 0.13$ ).

The anatomical distribution of target vessel orientation as measured by the four observers (mean angle) for the CA, SMA, LRA and RRA was  $18^\circ$ ,  $4^\circ$ ,  $80^\circ$  and  $-67^\circ$  (Fig. 3).

**Distance between target vessels.** The overall inter-observer measurement error between observers for distance between



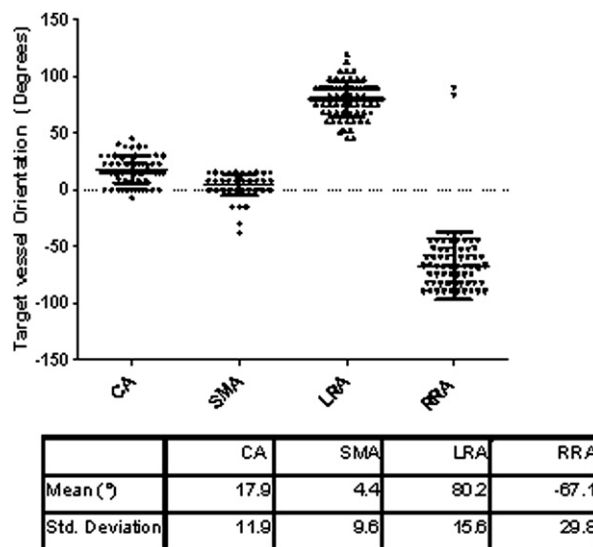
**Figure 2** Inter-observer measurement error of target vessel orientation showing means and 95% confidence intervals. (CA, Coeliac axis, SMA, superior mesenteric artery, LRA and RRA, left and right renal arteries respectively).

target vessels was  $\pm 5.3$  mm (4.4–6.2 95% CI). The inter-observer error in measurement of the distance from CA to SMA, RRA and LRA was  $\pm 5.0$  mm (3.5–6.5 95% CI),  $\pm 4.4$  mm (3.2–5.6 95% CI) and  $\pm 6.4$  mm (4.4–6.2 95% CI) respectively (Fig. 4). Variance between differences in measurement of all distances (CA-SMA, SA-LRA and CA-RRA) was not significant (ANOVA,  $p = 0.19$ ).

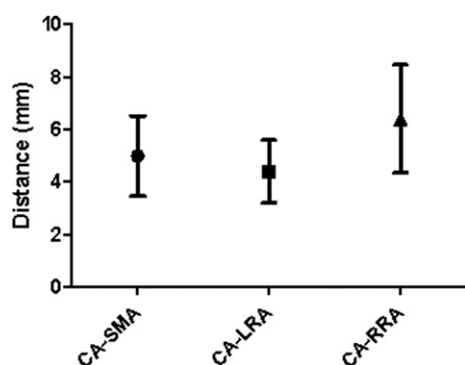
The mean distance as measured by the four observers between CA-SMA, CA-LRA and CA-RRA was 21 mm, 31 mm and 35 mm respectively (Fig. 5).

**Proximal stent diameter and component number.** All observers selected 2 internal stents. The median difference in internal stent-graft diameter was 1 stent size (Inter quartile range 0–2 stent sizes, one stent size = 2 mm difference). The maximum difference between observers was 4 stent sizes.

**Allocation of target vessel fenestration.** There was universal agreement for a scallop for the coeliac axis. 64 allocations (84%) (64/76) were for a scallop to the SMA with the rest (16%) allocating a large fenestration. Observers agreed on fenestration type for the SMA in 84% of cases.



**Figure 3** (Anatomical) distribution of target vessel orientation in degrees. Showing mean and SD.



**Figure 4** Inter-observer measurement error of the distance between CA and SMA, LRA and RRA, showing means and 95% confidence intervals.

Three out of four observers agreeing in a further 10% of cases.

As for the renal arteries, there was agreement in allocation in 94% of allocations for the left renal and 95% (72/76) of the time for the right renal. The majority of fenestrations allocated for the renal arteries were small fenestrations (97%).

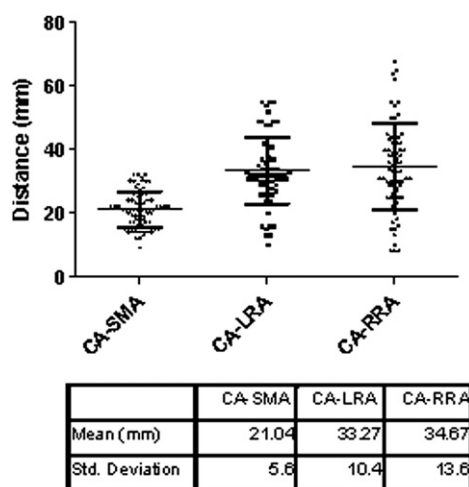
### Agreement with manufactured device

#### Target vessel fenestrations

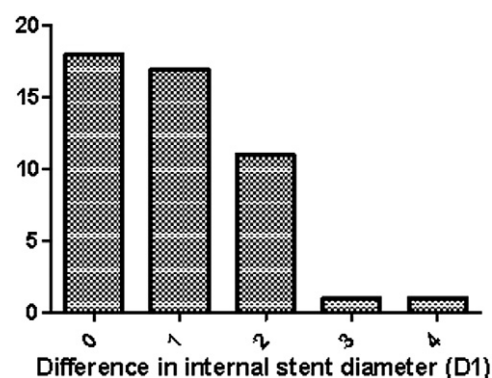
The overall mean difference of target vessel orientation between the manufactured devices and the four observers was  $-1.3^\circ$  (SD  $\pm 6.9$ ,  $-3.8$ – $1.2$  95% CI). The mean difference for the SMA was  $-2.6^\circ$  (SD  $\pm 8.0$ ,  $-8.0$ – $2.7$  95% CI). For the LRA and RRA  $2.3^\circ$  (SD  $\pm 4.8$ ,  $-1.1$ – $5.7$  95% CI) and  $-3^\circ$  (SD  $\pm 6.8$ ,  $-7.3$ – $1.2$ ) (Fig. 7). There was no significant variance in the mean difference between the target vessels and the manufactured devices for the four target vessels measured (CA, SMA, LRA and RRA) (ANOVA,  $p = 0.15$ ).

#### Allocation of fenestration size

For the SMA, there was concordance with the manufactured device in 83% of allocations for fenestration size (scallop,



**Figure 5** Distribution of distance (mm) between CA and SMA, LRA and RRA. Scatter plot showing mean distance, error bars represent standard deviation.



**Figure 6** Frequency distribution of the deviation of measured internal stent diameters from actual manufactured stent-graft diameters.

large or small, 40/48). The disagreement between observers and manufactured stent-grafts where, allocating scallop where the actual device was a fenestration for SMA in 7 cases and 1 where fenestration was suggested and a scallop was actually made.

There was higher agreement between observers in allocating fenestrations for the left and right renal arteries (mainly small fenestrations, 94% and 95% of cases respectively).

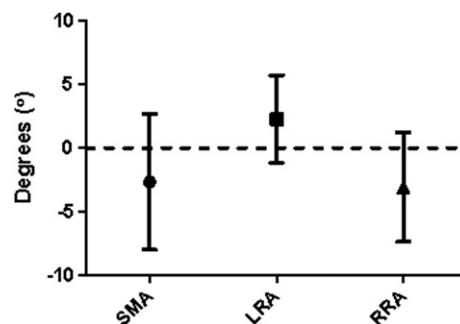
#### Internal stent diameter

The interquartile range (IQR) for the difference in internal stent diameter stent size between the observers and the manufacturer was 2. This ranged from undersizing to oversizing by one stent size in each direction ( $-1$  to  $1$  stent size difference). The maximum difference was 4 stent sizes (Fig. 6).

#### Stent-graft component lengths and distal limb diameters

The interquartile range of the difference in measurement between observers and manufacturer was 1 for both the ipsilateral limb diameter (D3) and contralateral limb diameter (D4) with a tendency of the observers to undersize compared to the manufacturer (IQR 0 to  $-1$  stent size).

As for the proximal graft length (L1), the interquartile range was 2. For the distal body length (L2), ipsilateral limb length (L3) and contralateral limb length (L4), the interquartile range was 1. There was a tendency to oversize by the observers compared to the manufacturer particularly



**Figure 7** Mean difference and 95% confidence interval between observer target vessel orientation and manufactured stent-graft. (0 = agreement with manufacturer).



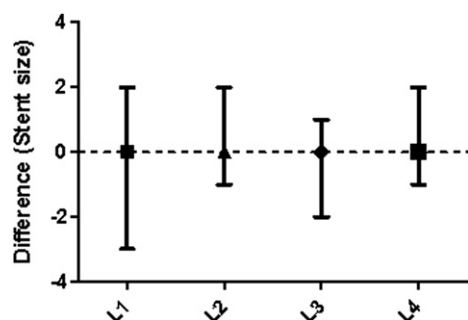
for the distal body length (L2) and contralateral limb (L4) (Fig. 8).

## Discussion

To investigate the level of agreement in morphological assessment and device planning for juxtarenal aneurysms, four experienced observers in four different institutions performed morphological assessment and planned fenestrated devices independently as they would do in their normal clinical practice. A standard proforma was provided but specific methodology to obtain these measurements was intentionally avoided to simulate “real world” routine clinical practice.

At first glance, there appears to be little agreement between observers on target vessel orientation (angle) with only 7% of all angles being chosen by all the four observers. On closer examination, the variability in measurement as expressed by the inter-observer measurement error was slight. This was lowest for SMA ( $\pm 10^\circ$ ). The highest variability was for LRA, but this was only just over  $15^\circ$ . There is no consensus regarding maximum tolerance levels in clinical practice between fenestration orientation and target vessel orientations. Some experienced endovascular specialists have suggested that a tolerance level of  $15^\circ$  was considered acceptable as a smaller difference between fenestration and target vessel is unlikely to lead to a clinically significant event.<sup>7</sup> Despite using different workstations and sizing methodology, the overall inter-observer error was less than the suggested level of tolerance of  $15^\circ$ .

All observers selected 2 internal stents. This may reflect the guidance from stent-graft manufacturers as having 2 internal stents potentially offers better seal and more flexibility in positioning the fenestration. There was agreement on internal stent diameter in 21% of cases (16/76). The median inter-observer difference in internal stent diameter was 1 stent size. With a total of 58% of internal stent diameter measurements differing by only one stent size which is considered by some a clinically acceptable variation.<sup>7,8</sup> It would be expected that the agreement would be higher for the internal stent-graft diameter. On further examination of the frequency distribution, the difference was 2 stents or less in 75% of cases. This would translate into a difference of the internal stent diameter by 4 mm.



**Figure 8** Difference between observer recommendations for distal body length (L2), ipsilateral and contralateral limb length (L3, L4) and manufactured stent-graft. (median and range, 0 = agreement with manufacturer).

A comparison between the devices planned by the four observers and actual manufactured devices is useful. Recently there has been interest in developing “off the shelf” fenestrated stent-grafts that would be stored in central repositories containing a finite number of fenestrated devices that would enable treatment of the majority of patients with juxtarenal aneurysms.<sup>7,9</sup>

It is important then to assess the degree of variability in planning as performed by different experienced operators. The overall mean difference of target vessel orientation between the manufactured devices and the four observers was  $-1.3^\circ$  (SD  $\pm 6.9$ ). There was concordance with target vessel orientation as per the manufactured device in 35% of measurements. However, 94% of target vessels were within  $15^\circ$  of the fenestration eventually manufactured with only 6% falling outside this range (Table 1).

The observers’ recommendations for the internal stent diameter agreed with those of the manufacturer in 38% of measurements. With another 35% being within one stent size. This left only 27% of measurements outside the tolerance range. As for allocating fenestration type, there was agreement with the manufactured devices in 83% of cases when allocating a fenestration type for the SMA and a higher percentage (94–95%) for renal arteries.

As expected, there was less agreement in distal device lengths and diameters between observers and the manufacturer (Fig. 8). This reflects individual preferences on main body and limb lengths. Some would prefer longer main body with shorter limb lengths. This becomes more variable when the degree of overlap is also considered.

Case selection for this study was for patients who underwent successful endovascular repair of juxtarenal aneurysms with fenestrated stent-grafts that would have been unsuitable candidates for repair with a standard stent-graft. CT scans of patients with suprarenal aneurysms and morphology that would pose a relative contraindication by some for repair with a fenestrated device such as a severely angulated or no infrarenal neck were excluded. So there would be no surprise that all observers agreed on the number of fenestrations for each case. However, in respect of all other measurements and planning, observers used different workstations in different institutions and were blinded to the actual device that was manufactured.

Ideally a larger number of cases would have been desirable, but was prohibited in part due to the strict inclusion criteria, excluding any patient with equivocal morphology or suboptimal CT scans needed for the different workstations. Also, performing a detailed morphological assessment and planning fenestrated stent-grafts is complex and time consuming in some cases compared to endovascular planning for infrarenal aneurysms. Obtaining manufacturer planning data for all cases would have been desirable, but it was only possible to

**Table 1** Agreement with manufactured device for target vessel orientation.

	Agreement (%)	$\pm 15^\circ$ (%)	$> 15^\circ$ (%)
SMA	20 (42)	24 (50)	4 (8)
LRA	14 (29)	26 (54)	4 (8)
RRA	15 (31)	32 (67)	1 (2)

obtain complete planning data from the device manufacturer for 12 cases.

Accuracy is essential in planning fenestrated endovascular aneurysm repair.<sup>5,6</sup> The use of 3 dimensional workstations has made this task easier but there are still some concerns over intra and inter-observer variability.<sup>8,10,11</sup> Recently, it has been shown that this problem is significant in a small percentage of patients.<sup>12</sup> Standardisation of terminology relating to juxtarenal aneurysms is lacking currently and may improve the communication of results and act as a guide in treatment.

It is still not entirely clear if the tolerance limits referred to above are over constrictive or too lax. Early in the experience with fenestrated stent-grafts, planning was performed using axial CT images that don't accurately represent in vivo vessel orientation, with satisfactory results. Aortic morphology is altered during the cardiac cycle, and as cardiac gated CT is not widely used in routine practice this effect is currently ignored on standard CT imaging.<sup>13</sup> Furthermore, insertion of stiff wires and the aortic stent-graft will change the native morphology.<sup>8,11</sup> It is also likely that with the development of more advanced, low profile flexible stent-grafts, that a greater degree of flexibility could be accepted.

Endovascular repair with fenestrated stent-grafts is associated with lower perioperative morbidity and mortality compared to open surgery.<sup>3,14,15</sup> Data on medium term durability and target vessel patency is favourable and long-term outcomes are awaited.<sup>1,2</sup> The custom made nature of these devices has so far limited their applicability due cost and the necessary delay in manufacture.

The concept of central repositories of readymade off the shelf fenestrated devices is gaining interest and looks like a potentially realistic prospect in the near future.<sup>7,9</sup> This might make fenestrated technology available to more patients, particularly those with emergency presentation, and will reduce cost. With solutions to increase applicability on the horizon, it would seem logical for appropriately trained endovascular specialists in regional centres to be able to size and plan fenestrated stent-grafts.<sup>7,9</sup> Not only to decrease the time lag to manufacture but also, potentially to be able to choose suitable fenestrated stent-grafts "off the shelf" thus offering this modality in the emergency setting and for those who are at risk of rupture and cannot wait for the current 6–8 weeks time required for customisation.

In conclusion there was an overall high level of agreement both between observers and the stent-graft manufacturer in the majority of cases. This is despite the fact that the observers performed the measurements independently, in different institutions using different methods of assessing morphology and planning.

## Conflict of Interest Disclosure

AHM: None, TAR: None, MJB: None, BJM: None, JP: None, IML: None, MMT: None, RJH: None.

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